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(54) Title: AN ELECTRO-STIMULATION DEVICE

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(57) Abstract: The present invention relates to an electro-stimulation device (1) where the supplementary motor area, premotor area and/or subthalamic nucleus is stimulated extracranially via intrinsic auricular muscles and the stimulation intensity of the supplementary motor area, premotor area and/or subthalamic nucleus is changed with the intensity of the tremors. The inventive electro-stimulation device (1) essentially comprises; at least two electrodes (2) which enables sending and receiving electric signals, at least one control unit (6) which produces stimulating signals for reducing/resting over activities such as tremors and enables these signals to be sent/received from electrodes (2).

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DESCRIPTION
AN ELECTRO-STIMULATION DEVICE

Field of the invention

The present invention relates to an electro-stimulation device where the supplementary motor area, premotor area and/or subthalamic nucleus are stimulated extracranially.

Background of the invention

Stimulation of the subthalamic nucleus and as a consequence, activations of the supplementary motor areas and premotor areas and normalization of the abnormal resting over activity in the motor system are the primary targets of the deep brain stimulation devices. Abnormal resting over activity as tremors can be caused by conditions or medicines that affect the nervous system, including Parkinson's disease, liver failure, alcoholism, mercury or arsenic poisoning, lithium, and certain antidepressants. Rigidity, bradykinesia and dyskinesia are other symptoms of the Parkinson's disease besides tremors.

Current applications to stimulate subthalamic nucleus includes intracranial electrode placement, which is called deep brain stimulation. The process of deep brain stimulation of the subthalamic nucleus requires a neurosurgery, which is an extremely invasive intervention for the Parkinson's patient. Further, surgical device applications are likely to have side effects. Moreover, the battery of the stimulator is placed under the thorax skin while the electrodes inserted into the brain tissue and the wires goes under the skin. The frequency and the intensity of these stimulators can be altered wirelessly with an external unit.

The United States patent application numbered US5707396 discloses a method of arresting degeneration of the substantia nigra by high frequency stimulation of
subthalamic nucleus. This method needs the electrodes to be neurosurgically implanted into substantia nigra besides surgical implantation of the battery.

The European patent document numbered EP2474339 discloses a Resuscitation device for resuscitation by stimulating an auricle of a human ear.

**Objects of the invention**

The object of the invention is to provide an electro-stimulation device where the supplementary motor area, premotor area and/or subthalamic nucleus is stimulated extracranially.

Another object of the invention is to provide an electro-stimulation device where the supplementary motor area, premotor area and/or subthalamic nucleus is stimulated via auricular muscles.

Another object of the invention is to provide an electro-stimulation device where the stimulation intensity of the supplementary motor area, premotor area and/or subthalamic nucleus is changed with the intensity of the tremors.

**Detailed description of the invention**

An electro-stimulation device in order to fulfill the objects of the present invention is illustrated in the attached figures, where:

**Figure 1** is the schematic view of one embodiment of an electro-stimulation device.

**Figure 2** is the schematic view of another embodiment of an electro-stimulation device.

Elements shown in the figures are numbered as follows:
1. Electro-stimulation device
2. Electrode
3. Driving circuit
4. Sensing unit
5. Communication unit
6. Control unit
7. Remote unit
8. Ground electrode

10 The inventive electro-stimulation device (1) essentially comprises;
   - at least two electrodes (2) which enables sending and receiving electric signals and that are adapted to be attached to intrinsic auricular muscles such as helicis major, helicis minor, tragus, anti-tragous etc,
   - at least one control unit (6) which produces stimulating signals for reducing resting over activities such as tremors and enables these signals to be sent to/received from electrodes (2),
   - a ground electrode (8) which provides closing of the loop for the electrical current by providing an electrical path to the negative terminal of a power supply

20 In one embodiment of the invention, the electro-stimulation device (1) comprises at least one driving circuit (3) which provides voltage or current amplified signal from the control unit (6) to the electrodes (2).

25 In one embodiment of the invention, the electro-stimulation device (1) comprises at least one sensing unit (4) which enables receiving data from a patient. The signals to be sensed and the signals for stimulating can be carried via separate or the same electrodes (2). In the preferred embodiment of the invention, signals to be sensed and the signals for stimulating can be carried via the same electrodes (2). In this embodiment different time slots are allocated for signals to be sensed and the signals for stimulating, thus multiplexing the said signals. Another method
for tell the sensed signals and the signals for stimulating is to filter out the signals for stimulating that is generated by the control unit (6). It should be known that different methods for multiplexing the said signals such as space-division multiplexing, time-division multiplexing, code-division multiplexing etc. could also be utilized. The methods for multiplexing the said signals are not limited to those disclosed above.

In one embodiment of the invention, the electro-stimulation device (1) comprises at least one communication unit (5) which enables realizing communication with other devices,

In one embodiment of the invention, the electro-stimulation device (1) comprises at least one remote unit (7) which enables receiving data from the control unit (6) and/or changing settings of the control unit remotely.

In the preferred embodiment of the invention, the electro-stimulation device (1) comprises,

- at least two electrodes (2) which enables sending and receiving electric signals,

- at least one driving circuit (3) which enables providing power higher than the power limit of the control unit (6) to the electrodes (2) by controlling a power supply,

- at least one sensing unit (4) which enables receiving data from a patient,

- at least one communication unit (5) which enables realizing communication with other devices

- at least one control unit (6) which enables signals to be sent to/received from electrodes (2), controlling the driver (3), receiving signals from the sensing unit (4) and controlling the communication unit (5),

- at least one remote unit (7) which enables receiving data from the control unit (6) and/or changing settings of the control unit remotely,
In the preferred embodiment of the invention, the electro-stimulation device (1) comprises at least two electrodes (2), which enable sending and receiving electric signals in order to stimulate especially supplementary motor area, premotor area and/or subthalamic nucleus. In the preferred embodiment, these electrodes (2) are attached to intrinsic auricular muscles such as helicis major, helicis minor, tragicus, anti-tragicus etc. In this embodiment, the signal for stimulating the supplementary motor area, premotor area and/or subthalamic nucleus is produced by the control unit (6) and fed directly to the electrodes (2). In another embodiment of the invention, multiple electrodes (2) are used on the same part or different parts of the body. In a preferred embodiment, one electro-stimulation device can be placed on the aforementioned locations on the left ear and the other one on the right ear. The ground electrode (8) closes the loop for the electrical current by providing an electrical path to the negative terminal of the power supply. It can be a small conductive contact or a pad with several cm² area. The ground electrode (8) connection can be at the back of the ear, neck, scalp, or other places in the proximity of the electrode (2).

In one embodiment of the invention, the electro-stimulation device (1) comprises at least one sensing unit (4) which enables making measurements related to the status of the patient's disease. The sensing unit (4) can be a camera, which enables receiving images from the patient and hence enabling visually monitoring the symptoms such as tremors. The received images are then processed by image processing techniques and information such as the intensity of the tremors is acquired.

In one embodiment of the invention, one of the at least one sensing unit (4) is an accelerometer. In this embodiment, the sensing unit (4) is attached to the limb, the activity of which is wanted to be known. In this embodiment, sensing unit (4) is used to sense the intensity of disturbances by measuring the acceleration of the limb, to which the sensing unit (4) is attached. Upon measuring the disturbance
level, the stimulation signal is adjusted so that it can compensate the said disturbance level. In this embodiment the measurement of the disturbance level is conducted periodically so that the stimulation signal can be adapted to the changing status of the patient. In this embodiment, sensing unit (4) may utilize a dedicated control unit and a dedicated communication unit in order to transfer the results of the measurements to the control unit (6) wirelessly. The adjustments to the said signal can be induced by changing the amplitude, frequency, pulse width, and pulse shape such as the harmonic content of the periodic pulses, or the phase between the electro-stimulating device if more than one stimulator is used.

In one embodiment of the invention, the sensing unit (4) is a signal receiver, which utilizes the electrodes (2) in order to receive the signals passing by the muscles to which these electrodes (2) are attached. In this embodiment, sensing unit (4) is used to sense the intensity of disturbances by measuring the signals during a resting period. Upon measuring the disturbance level, the stimulation signal is adjusted so that it can compensate the said disturbance level. In this embodiment the measurement of the disturbance level is conducted periodically so that the stimulation signal can be adapted to the changing status of the patient.

In the preferred embodiment, the electro-stimulation device (1) comprises at least one communication unit (5) which enables communication with other devices such as remote control units, computers, measurement units etc. The communication unit (5) may utilize communication standards including but not limited to IR, USB, firewire, ethernet, IEEE802.11, Bluetooth, RF communication interface, RS-232, RS-422, RS-485, SPI (serial peripheral interface) i2c, as well as proprietary interfaces and/or protocols and such.

In one embodiment of the invention, the signal for stimulating the supplementary motor area, premotor area and/or subthalamus nucleus is produced by the control unit (6) and the signal is used to trigger a driving circuit (3), instead of being fed directly to the electrodes (2). This driving circuit enables driving powers greater
than control unit (6) is able provide, from a power source. In this application, the driven power is fed to the electrodes (2) by the driving circuit (3).

In one embodiment of the invention, the sensing unit (4) comprises a dedicated control unit and a dedicated communication unit. In this embodiment, the sensing unit (4) is not directly attached to the control unit (6) and instead, it is linked to the control unit (6) via the dedicated communication unit and the communication unit (5). In this embodiment, the sensing unit (4) processes the acquired data using the dedicated control unit and sends the resulting data to the control unit (6) via the link between the dedicated communication unit and the communication unit (5). Control unit (6) receives the sent data via the communication unit (5).

In one embodiment of the invention, the remote unit (7) is used for changing working parameters of the control unit (6). In this embodiment, the measurements conducted by the sensing unit (4) can be acquired by the remote unit (7) as well. The remote unit may utilize a display unit, which can be used to display the data acquired from the control unit (6) directly on the remote unit (7). The remote unit (7) may also utilize interfaces including but not limited to USB, RS-232, RS-485, bluetooth and such, in order to provide connectivity with terminals including but not limited to desktop computers, portable computers, handheld computers, tablet computers, smart phones and proprietary units. In this embodiment, the working parameters of the control unit (6) can be monitored and changed via these terminals. It should be clearly understood that the remote unit (7) utilizes dedicated communication interfaces in order to communicate with the control unit (6). These interfaces include, but they are not limited to, IR, USB, firewire, ethernet, IEEE802.11, Bluetooth, RF communication interface, RS-232, RS-422, RS-485, SPI (serial peripheral interface) i2c, as well as proprietary interfaces and/or protocols and such.

In the preferred embodiment of the invention, the stimulating signal produced by the control unit (6) has the voltage of 0V-15V and the frequency of 2Hz-200Hz.
The voltage and the frequency of the stimulating signal can be automatically changed depending on the situation of the patient by the control unit (6) or it can be remotely changed via the remote unit (7) by an authorized user such as a physician, upon evaluating the situation of the patient.
CLAIMS

1. An electro-stimulation device (1) comprising;
   - at least two electrodes (2) which enables sending and receiving electric signals,
   - at least one control unit (6) which enables signals to be sent to/received from electrodes (2)
   - a ground electrode (8) which provides closing of the loop for the electrical current by providing an electrical path to the negative terminal of a power supply and characterized by
   - the control unit (6) which produces stimulating signals for reducing resting over activities such as tremors
   - the electrodes (2) that are adapted to be attached to intrinsic auricular muscles such as helicus major, helicus minor, tragicus, anti-tragicus etc

2. An electro-stimulation device (1) as in Claim 1 characterized in that it further comprises at least one sensing unit (4) which enables receiving data from a patient.

3. An electro-stimulation device (1) as in any of the above claims characterized in that it further comprises at least one communication unit (5) which enables realizing communication with other devices such as remote control units, computers, measurement units etc.

4. An electro-stimulation device (1) as in any of the above claims characterized in that it further comprises at least one remote unit (7) which enables receiving data from the control unit (6) and/or changing settings of the control unit remotely.

5. An electro-stimulation device (1) as in any of the above claims characterized in that it further comprises at least one driving circuit (3) which enables
providing power higher than the power limit of the control unit (6) to the electrodes (2) by controlling a power supply.

6. An electro-stimulation device (1) as in any Claims 2-5 characterized in that one of the at least one sensing unit (4) can is a camera, which enables receiving images from the patient and hence enabling visually monitoring the symptoms such as tremors.

7. An electro-stimulation device (1) as in Claim 6 characterized in that the intensities of the tremors are acquired by processing the received images by image processing techniques.

8. An electro-stimulation device (1) as in any Claims 2-7 characterized in that one of the at least one sensing unit (4) is an accelerometer which is used to sense the intensity of disturbances by measuring the acceleration of the limb, to which the sensing unit (4) is attached.

9. An electro-stimulation device (1) as in Claim 8 characterized in that the sensing unit (4) is used to sense the intensity of disturbances by measuring the acceleration of the limb, to which the sensing unit (4) is attached.

10. An electro-stimulation device (1) as in Claims 2-9 characterized in that the sensing unit (4) utilizes a dedicated communication unit in order to transfer the results of the measurements to the control unit (6) wirelessly.

11. An electro-stimulation device (1) as in Claims 10 characterized in that the sensing unit (4) comprises a dedicated control unit and a dedicated communication unit so that the sensing unit (4) is not directly attached to the control unit (6) and instead, it is linked to the control unit (6) via the dedicated communication unit and the communication unit (5).
12. An electro-stimulation device (1) as in Claims 10 characterized in that the sensing unit (4) processes the acquired data using the dedicated control unit, processes it and sends the resulting data to the control unit (6) via the link between the dedicated communication unit and the communication unit (5).

13. An electro-stimulation device (1) as in Claims 2-12 characterized in that the sensing unit (4) is a signal receiver, which utilizes the electrodes (2) in order to receive the signals passing by the muscles to which these electrodes (2) are attached.

14. An electro-stimulation device (1) as in Claim 13 characterized in that the sensing unit (4) is used to sense the intensity of disturbances by measuring the signals passing from the muscles to which said electrodes (2) are attached, during a resting period.

15. An electro-stimulation device (1) as in Claims 2-14 characterized in that the stimulation signal is adjusted upon measuring the disturbance levels so that it can compensate the said disturbances.

16. An electro-stimulation device (1) as in Claims 2-15 characterized in that the measurement of the disturbance level is conducted periodically so that the stimulation signal can be adapted to the changing status of the patient.

17. An electro-stimulation device (1) as in Claims 5-16 characterized in that the signal for stimulating the supplementary motor area, premotor area and/or subthalamic nucleus is produced by the control unit (6) and the signal is used to trigger a driving circuit (3), instead of being fed directly to the electrodes (2).

18. An electro-stimulation device (1) as in Claims 4-17 characterized in that the remote unit (7) is used for changing working parameters of the control unit.
19. An electro-stimulation device (1) as in Claims 4-18 characterized in that the measurements conducted by the sensing unit (4) can be acquired by the remote unit (7) as well.

20. An electro-stimulation device (1) as in Claims 4-19 characterized in that the remote unit (7) utilizes a display unit, which can be used to display the data acquired from the control unit (6) directly on the remote unit (7).

21. An electro-stimulation device (1) as in Claims 4-20 characterized in that the remote unit (7) utilizes interfaces including but not limited to USB, RS-232, RS-485, bluetooth and such, in order to provide connectivity with terminals including but not limited to desktop computers, portable computers, handheld computers, tablet computers, smart phones and proprietary units.

22. An electro-stimulation device (1) as in Claim 21 characterized in that the working parameters of the control unit (6) can be monitored and changed via the said terminals.

23. An electro-stimulation device (1) as in Claims 4-22 characterized in that the remote unit (7) utilizes dedicated communication interfaces in order to communicate with the control unit (6) including but not limited to IR, USB, firewire, ethernet, IEEE802.11, Bluetooth, RF communication interface, RS-232, RS-422, RS-485, SPI (serial peripheral interface) i2c, as well as proprietary interfaces and/or protocols and such.

24. An electro-stimulation device (1) as in any of the above claims characterized in that the stimulating signal produced by the control unit (6) has the voltage of 0 V-15 V and the frequency of 0 Hz-200 Hz.
25. An electro-stimulation device (1) as in Claims 4-24 characterized in that the situation of the patient is determined by the control unit (6) upon evaluating the data provided by the sensing unit (4) and the characteristics of the stimulating signal such as amplitude, frequency, pulse width, pulse shape and the phase between the pulses of the stimulating signal are changed automatically depending on the situation of the patient by the control unit (6).

26. An electro-stimulation device (1) as in Claims 4-25 characterized in that the characteristics of the stimulating signal such as amplitude, frequency, pulse width, pulse shape and the phase between the pulses of the stimulating signal can be remotely changed via the remote unit (7) by an authorized user such as a physician, upon evaluating the situation of the patient using the data acquired by the sensing unit (4).
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/Q5 A61N1/36 A61N1/Q4

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C. See patent family annex.

Date of the actual completion of the international search 13 December 2013
Date of mailing of the international search report 07/01/2014

Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer Scheffler, Arnaud
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